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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/971,774	10/09/2001	H. Paul Redmond	1194-180	3168

6449 7590 09/24/2003

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EXAMINER
MAIER, LEIGH C

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/971,774	Applicant(s) Redmond
	Examiner Leigh Maier	Art Unit 1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 8, 2003* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-12 and 26* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-12 and 26* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the Claims

Claims 13-25 have been cancelled. Claims 1-12 and 26 are pending. Any objection or rejection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 U.S.C. § 103

Claims 1-5, 8, 9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over JACOBI et al (Langenbecks Arch. Chir., 1997) in view of MONSON et al (WO 92/00743).

Applicant's arguments filed July 8, 2003 have been fully considered but they are not persuasive. It appears that Applicant's arguments are directed exclusively to the rejection based on 35 U.S.C. § 102. The examiner notes that the claims were incorrectly grouped under this rejection, so that claim 1 was rejected as being anticipated when it was claim 13 that was intended. Furthermore, all the limitations were addressed but directed at claims that were cancelled. However, due to the mis-grouping in the previous action, this action will not be made final, but the original action will be repeated with the intended claim grouping. Applicant has requested independent consideration of claims 3, 4, 6, and 10 and contends that no combination of the cited references suggest these embodiments. The examiner maintains that all these limitations were addressed previously but will be repeated herein.

The claims are drawn to a method of treating abdominal cancer comprising perfoming surgery to remove a cancerous tumor wherein the method includes a step of administering a solution of taurolidine and/or taurultam to the patient's abdomen prior to closing surgical opening along with an additional step of adminstering taurolidine and/or taurultam after closing surgical opening. Dependents are drawn to further limitations concerning the administration of the taurolidine/taurultam solution - administration before surgery, mode of administration, concentration of the solution, administration of other components, and types of cancers.

JACOBI teaches that the intraperitoneal adminstration of taurolidine or a combination of taurolidine and heparin at the time of laparoscopic surgery for tumor removal reduces the incidence of tumor growth and trocar metastases. See abstract. The reference discloses that lavage with taurolidine and heparin is performed in human patients undergoing laparoscopic resection of malignancies. See last paragraph of the reference on page S35. In this discussion of the laparoscopic procedure in human patients, the reference does not explicitly describe the use of a trocar in this procedure in this passage. However, the reference is drawn to the decreased incidence of trocar metastases, so the use of this instrument is clearly implied.

The reference does not teach the use of taurultam in the concentration range recited in this procedure or the use such a solution before surgery or after closing. Neither does the reference specifically address the full range of cancer types recited in the claims.

MONSON teaches that taurolidine and taurultam are functional equivalents as both antibacterials and *antitumorals*. See all of page 1. The reference further teaches that the agents

are particularly beneficial for the prevention of the spread of metastases, especially following surgical removal of tumors of any type, including lymphomas, sarcomas, melanomas, and carcinomas. See page 3, second paragraph. Patients in need of metastasis prevention would include those scheduled for cancer surgery and those who have had cancer surgery. The reference teaches administration of the solution by injection or infusion.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer a solution of taurolidine and/or taurultam (with or without heparin) during laparoscopic cancer surgery. MONSON had taught that these species (taurolidine and/or taurultam) are functional equivalents for the inhibition of metastases. In the absence of unexpected results, one of ordinary skill would reasonably expect success in the use of taurolidine and/or taurultam for this art-disclosed utility. It would be within the scope of the artisan to optimize the solution concentration with routine experimentation.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer a solution of taurolidine and/or taurultam before and/or after cancer surgery for the benefits of treating malignancies as well as prevention of metastases, taught by MONSON. It would be further obvious to use this procedure for all of the recited cancers with a reasonable expectation of success. It would be within the scope of the artisan to select any common type of adminstration, such as IV or catheter, to adminster the solution.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over JACOBI et al (Langenbecks Arch. Chir., 1997) in view of MONSON et al (WO 92/00743) and further in view of ALLGOOD et al (US 5,176,651).

The invention is as set forth above. Claims 6, 7, and 10 are drawn to the use of a trocar comprising passing the taurolidine and/or taurultam solution through said trocar.

JACOBI and MONSON teach as set forth above. The references are silent regarding the adminstration of the taurolidine and/or taurultam solution by passing it through a trocar but does clearly suggest the use of a trocar for performing the surgical procedure.

ALLGOOD presents a brief discussion of the use of trocars and cannulas in endoscopic (laparoscopic) surgery. See col 1, lines 10-39. The reference teaches that laparoscopy typically comprises the use of a cannula inserted through a trocar for irrigation of the surgical site. By definition, irrigation comprises administration of a fluid to said site.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer taurolidine and/or taurultam in the JACOBI procedure via a cannula inserted through the trocar, as JACOBI had taught that the administration of the solution is beneficial in the prevention of trocar metastases. Fluid delivery via a cannula through a trocar in laparoscopy is standard procedure, as would be known to one of ordinary skill.

Claims 1-5, 8, 9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over JACOBI et al (Langenbecks Arch. Chir., 1997) in view of MONSON et al (WO 92/00743) and further in view of NICOLSON et al (US 5,262,403).

The invention is as set forth above. Claim 9 is drawn to the use of hyaluronic acid in combination with the taurolidine and/or taurultam.

JACOBI and MONSON teach as set forth above. The references teach the adminstration of the taurolidine and/or taurultam solution in combination with heparin but not hyaluronic acid.

NICOLSON teaches that glycosaminoglycans, such as heparin and hyaluronic acid, are useful for the inhibition of tumor-invasiveness and metastasis. See abstract and col 10, lines 4-10.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer the taurolidine and/or taurultam in combination with hyaluronic acid. JACOBI had taught that the administration of the taurolidine and/or taurultam in combination with heparin has utility in the prevention of metastasis. NICOLSON had taught that hyaluronic acid and heparin are functional equivalents for this utility. In the absence of unexpected results, one of ordinary skill would reasonably expect success in using hyaluronic acid in the JACOBI process.

Claims 1-5, 8, 9, 11, 12, and 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over JACOBI et al (Langenbecks Arch. Chir., 1997) in view of MONSON et al (WO 92/00743) and further in view of PHYSICIANS' DESK REFERENCE (PDR - 1995).

The invention is as set forth above. Claim 26 is drawn to the method further comprising adminstration of 5-FU at a dosage of about 0.1-1,000 mg.

JACOBI and MONSON teach as set forth above. The references do not teach the method further comprising adminstration of 5-FU. However, MONSON expressly suggests the administration of taurolidine and/or taurultam in combination with other anti-tumor therapuetics. See page 3, lines 1-7.

PDR teaches that 5-FU has utility in the treatment of a variety of the recited cancers, including colon, rectum, breast, and stomach. The suggested dosage is about 500 mg/day.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to add the administration of a known anti-tumor therapeutic agent, such as 5-FU to the method of JACOBI for the further treatment of cancer. In the absence of unexpected results, it would have been within the scope of the artisan to select any known anti-cancer agent for the combination of benefits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 14 of copending Application No. 10/270,174 in view of JACOBI et al (Langenbecks Arch. Chir., 1997).

Claim 14 of copending application '174 is drawn to the treatment of breast cancer comprising adminstration of taurolidine/taurultam before and after surgical removal of breast tumor. The claim does not specifically recite the administration of taurolidine/taurultam *during* surgery. JACOBI teaches as set forth above.

Although the claims are not identical, the claim of application '174 recites a narrower scope of cancer to be treated. Given the teaching of JACOBI, it would have been obvious to modify the method in the claim to administer taurolidine/taurultam during surgery in order to prevent surgical metastases.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525. The examiner can normally be reached on Monday-Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (703) 308-4624, may be contacted. The fax phone number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at http://**www.uspto.gov**. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier
Patent Examiner
September 22, 2003